

Monoterpene Hydrocarbons - Comments of Environmental Defense

(Submitted via Internet 10/23/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Monoterpene Hydrocarbons.

The Terpene Consortium, the Flavor and Fragrance High Production Volume Consortia, has submitted a Robust Summary/Test Plan to address available data and testing needs for five monoterpenes and seven mixtures consisting of primarily of one or more of these monoterpenes and closely related compounds. In support of this proposal, the Terpene Consortium has submitted a thorough and well-organized Test Plan that effectively complements an extensive and well-organized Robust Summary. The Robust Summary presents a compilation of experimental and calculated data describing the chemical/physical properties, environmental fate and toxicology of various members of the group. Chemicals addressed in this Robust Summary/Test Plan occur naturally to varying degrees in all plants, including fruits and vegetables normally consumed as food. As a result of their naturally occurring presence in fruits and vegetables, a normal diet accounts for greater than 90% of human exposure to most of these compounds. Being volatile constituents of plants, they are also naturally occurring components of the atmosphere. These chemicals are used primarily as flavors and fragrances and three of the five pure compounds (namely d-limonene, beta-myrcene and terpinolene) are considered "generally regarded as safe" (GRAS) by the U.S. Food and Drug Administration for their intended use as flavoring substances. All members of the group have closely related structures and properties and, in our view, it is appropriate that data developed for one or more members of the group be extrapolated to predict the environmental fate, ecotoxicity, and mammalian toxicity of other members of the group.

Limonene is the most extensively used of this group of chemicals and has been the most extensively studied. Studies of limonene fugacity and calculated data describing fugacity indicate that these monoterpenes partition primarily into the atmosphere where they react with hydroxyl radicals, ozone, and nitrate, and thus have a relatively short half-life. They also readily degrade in sludge and do not otherwise persist in the environment. Studies of the fate of limonene in humans and test animals mammals indicate that this chemical, which would be expected to be representative of the category, is rapidly absorbed, metabolized and excreted. There is no evidence that these chemicals would bioaccumulate in tissues. All available data indicate the monoterpenes have moderate to low toxicity to fish, invertebrates, plants and animals. They are negative in studies of genotoxicity and have low toxicity in repeat dose studies. Limonene has been the subject of extensive toxicological characterization by the National Toxicology Program. Results of these studies indicate that limonene has low toxicity and little or no potential for carcinogenicity when administered for the lifetime of the test animals. The most marked effects, spontaneous nephropathy and an increased incidence of kidney tumors, was determined to unique to the male rat and these results were not considered relevant to human health risks. Studies of the reproductive toxicity of limonene and beta myrcene indicate they do not pose a threat at doses that are not maternally toxic and thus are unlikely to pose a threat to human health at doses humans are likely to encounter.

The Test Plan submitted for the monoterpenes makes use of considerable calculated and bridged data based on structure/activity relationships; however, given the structural similarities and low toxicity of these chemicals we consider this acceptable. In summary, we consider the Test Plan for the monoterpenes acceptable as submitted.

Minor editorial note:

The second paragraph on page 27 is repeated as the third paragraph on at page.

Thank you for this opportunity to comment.

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